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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,236	09/24/2003	Allen House	LIFE-011CON	8136
24353	7590	11/21/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			HANDY, DWAYNE K	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/671,236

Applicant(s)

HOUSE ET AL.

Examiner

Dwayne K. Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/24/03, 10/8/04. 11-1-04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 21-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 of U.S. Patent No. 6,652,814. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 4-7 of '814 recite a test strip meter system comprised of a meter, a test strip and a test strip holder having a bump and a lip. Claim 3 defines the force required on the strip. Claims 3-7 of '814, then, fully encompass the device as claimed in instant claims 21-29.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 21-24, 29, 31, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Gassenhuber (4,934,817). Gassenhuber teaches a device with a detachable test strip holder for optically evaluating a test strip. The detachable test strip holder (18) is best shown in Figure 4. The strip holder provides a receiving groove (30) with a groove bottom (32) that slopes upward towards a support part (34) and cross piece (44) which is in an essentially parallel relationship with the support part (34) (col. 3, lines 34-47). When the test strip is placed in the holder the strip is placed between elements (34) and (44) and placed in the evaluating device, the surfaces engage the test strip in a sealing manner (see also Figure 5). Gassenhuber discloses the testing of blood in column 1, lines 12-14.

5. Claims 21-24, 31, 32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. (6,106,780). Douglas shows an analyte detection system.

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The system includes a testing or measuring instrument (21) for reading a sample that is contained on a test pad (12). The test pad is contained in a test strip (11) and holder (13), as well as a bottom portion (15). This is shown in Figures 1A and 1B and described beginning in column 5. As this pertains to the instant claims, the Examiner contends that the element (11) would constitute a strip holder, and the holder element (13) forms a sealing surface with the test strip when the device shown in Figures 1A and 1B are assembled. Since this entire assembly (elements 11-15) is removable the strip holder is "readily removable from the meter". Also, as shown in Figure 1A the holder (13) is configured to at least partially encompass a sample application region of the test pad (12). Douglas recites steps to use the device including providing the holder and analysis devices in column 10, lines 19-32.

### ***Inventorship***

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 25-28, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gassenhuber in view of Hones et al. (5,424,035). Gassenhuber, as described in paragraph 4 above teaches every element of claims 25-28, 35 and 36, except for the raised bump on the test holder and a specific amount of force placed on the test strip by the sealing element. Gassenhuber instead utilizes a receiving groove that guides a test strip into an area between two elements of the holder in a sealing engagement. Hones also shows a test strip analysis system that utilizes a strip holder. Their strip holder (3) contains a variety of elements for aligning and securing a test strip (4) including a "stationary pressure element" which amounts to a bump on the upper surface of the holder that extends down to the surface of the holder and helps to secure

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the strip. It would have been obvious to combine the teaching of a bump structure from the holder of Hones with the holder of Gassenhuber. Providing the biasing surface/element on the strip holder would provide additional alignment and securing features to the holder of Gassenhuber. This would be desirable for an optical analysis device. Also, Gassenhuber and Hones are silent as to the specific amount of force placed on the test strip (20) by both the lip and bump features when their holders are engaging a test strip in a sealing relationship. The Examiner contends that it would be obvious to one of ordinary skill in the art to provide a lip and bump members to provide a sealing alignment with enough force to provide the seal. The Examiner would also consider it well known within the art to use bumps either in the insertion chambers for the test strip or on their holder to provide alignment with the test device.

9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (6,106,780) in view of Anderson et al. (6,066,243). Douglas teaches every element of claim 33 except for a measurement of clotting time. Anderson teaches a portable medical analyzer that can perform a variety of diagnostic tests, including PT, PTT and ACT clotting tests (claim 13). It would have been obvious to one of ordinary skill in the art to combine the coagulation measurements from Anderson with the method of Douglas. One would add these tests to perform clotting tests in the blood as suggested by Anderson.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sohrab (5,714,123) teaches the placement of a protective shield over the sample receiving area of a test strip to prevent contamination of the sample. Patel et al. (6,335,203) discloses an optical test strip reading apparatus that uses a series of bumps in the insertion path to guide the strip to the analysis element. Poto et al. (5,795,543) shows a diagnostic kit that has guiding rails on the analysis device for guiding test strips. Connolly (5,597,532) teaches a test strip containing a hinged portion which folds over the sample/detection area. Markart et al. (5,281,395) recites a test strip analysis device that uses spring elements to press a test strip against a support. Markart (6,180,063) displays a measuring device that aligns the test strip through a series of apertures and notches in the strip. Nishikawa et al. (6,315,738) discloses an unit for collecting a body fluid that contains a test strip holder. Watlington, IV (4,797,256) displays a device for receiving and holding a test strip. Modzelewski et al. (6,458,326) teaches a testing apparatus with a test strip platform that defines a track for positioning and protecting the strip when inserted into the testing device.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

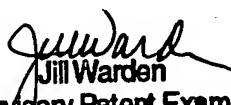


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH  
November 13, 2005

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700